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Customer No.: 07278

Docket No: 05432/100M029-US2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/750,049

Art Unit: Not Yet Assigned

Applicant : Hans PETERSEN et al.

Filed : December 30, 2003

Examiner: Not Yet Assigned

Title : CRYSTALLINE BASE OF CITALOPRAM

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In order to comply with 37 C.F.R. §§ 1.97 and 1.98, attached hereto is a copy of Form PTO/SB/08. Copies of the documents listed thereon were previously submitted during prosecution of the parent application, Serial No. 10/245,824, filed September 12, 2002.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each document cited (including any cited in applicant's specification which is not repeated on the attached PTO/SB/08) be given thorough consideration and that

it be cited of record in the prosecution history of the present application by initialing Form PTO/SB/08 next to the document. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

This Information Disclosure Statement is filed pursuant to 37 C.F.R. § 1.97(b)(3), before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fee is due. The Commissioner is authorized to charge any additional fees required in connection with this Information Disclosure Statement or credit any overpayment to Deposit Account No. 04-0100.

The present Information Disclosure Statement is being submitted in compliance with 37 C.F.R. § 1.56, but the citation of such documents is not to be construed as an admission that such documents are necessarily relevant or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner, in the normal course of examination, will make an independent search and will determine the best prior art consistent with 37 C.F.R. § 1.104(a) and in the course of each search, will review for relevance every document cited on the attached form even if not initialed.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

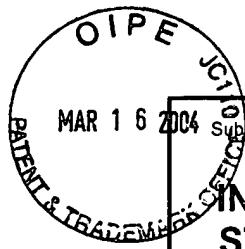
Dated: March 16, 2004

By:

  
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Substitute for form 1449A/B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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				Filing Date December 30, 2003
				First Named Inventor Hans Petersen
				Art Unit Not Yet Assigned
				Examiner Name Not Yet Assigned
Sheet	1	of	7	Attorney Docket Number 05432/100M029-US2

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
1.		2002/0061925	05-23-2002	Petersen et al.	
2.		2001/0049450	12-06-2001	Ikemoto et al.	
3.		5,523,423	06-04-1996	Murthy et al.	
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13.		2,584,429	02-05-1952	Croxall et al.	
14.		2,233,970	03-04-1941	Andersag et al.	

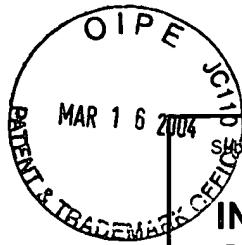
### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
15.		WO 03/007872	01-30-2003	Sathyaranayana et al.		
16.		GB 2375763	11-27-2002	Matrix Laboratories Limited		
17.		WO 02/072565	09-19-2002	Biswas et al.		
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Sheet	2	of	7	Attorney Docket Number	
05432/100M029-US2					

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36.	WO 98/28293	07-02-1998	H. Lundbeck A/S		
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### NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	49.	Kirk-Othmer, <i>Encyclopedia of Chemical Technology</i> , Second Edition, Volume 6: 482, New York: John Wiley & Sons (1965)	
	50.	Kunsemüller, Johannes, Ed., <i>Meyers Lexikon der Technik und der exakten Naturwissenschaften</i> : 1151, Mannheim/Wien/Zurich: Bibliographisches Institute (1970)	
	51.	Bates, Robert B., et al., Ed., <i>Research Techniques in Organic Chemistry</i> : 50-52, Englewood Cliffs, NJ: Prentice-Hall, Inc. (1971)	
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	53.	Hyttel, John, "Citalopram - Pharmacological Profile of a Specific Serotonin Uptake Inhibitor with Antidepressant Activity," <i>Prog. Neuro-Psychopharmacol &amp; Biol. Psychiat.</i> 6: 277-295 (1982)	
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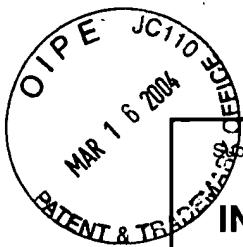


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				Filing Date	December 30, 2003
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75.	Notice of Opposition filed on behalf of: neuraxpharm Arzneimittel GmbH & Co. KG, dated 9/5/02
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77.	Notice of Opposition filed on behalf of: Stada-Arzneimittel Aktiengesellschaft (with English Translation)
78.	Notice of Opposition filed on behalf of: RATIOPHARM GMBH
79.	Notice of Opposition filed on behalf of: hexal Pharma GmbH
80.	Notice of Opposition filed on behalf of: Tiefenbacher Alfred E.Gmb & Co.
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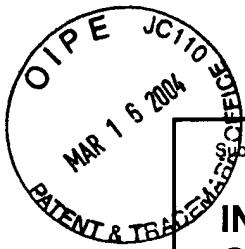
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Sheet	4	of	7	Attorney Docket Number	05432/100M029-US2

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93.	Topics in Stereochemistry, vol. 6 (eds. N.L. Allinger & E.L. Eliel), S.H. Wilen, Resolving Agents and Resolutions in Organic Chemistry, pp. 107-176 (published in or about 1971).
94.	Declaration of Dr. C. Satyanarayana, Maufacturing Process for Citalopram Hydrobromide
95.	Statement of Peter Somfai, Professor, dated 02/05/03
96.	Declaration of Karl Anker Jorgensen, dated 05/03/02
97.	Opinion of Torbjorn Norin, dated 05/03/02
98.	Declaration of Karl Anker Jorgensen, dated 07/10/03
99.	Kankan, R.N., Cipla Manufacturing & Research Division, Test results of Example 3 in EP 0347066, dated 03/08/02
100.	Kankan, R.N., Cipla Manufacturing & Research Division, Citalopram-methylester results, dated 5/29/02
101.	Third party observation in accordance with Art. 115 EPC regarding European Patent Application No. EP01 909 568.6-2117, in the name of H. Lundbeck A/S; Maiwald Patentanwalts GmbH
102.	Supplemental Declaration of Karl Anker Jorgensen, dated 07/10/03
103.	Report, Dr. U. Riederer- Cyanation of 5-Bromocitalopram by the "Matrix Method" - 21 and 22 October 2002
104.	Vogel, A.I., A Textbook of Practical Organic Chemistry including Qualitative Organic Analysis, preface, pp. 122-129
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111.	Casey, M. et al., Advanced Practical Organic Chemistry, Blackie, 1990, p. 155
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113.	Declaration of Erik Fischer, Krystallisation af citaloprambase fra aprotiske oplosningmidler, dated 11/07/02
114.	Declaration of Olov Sterner, Professor, dated June 10, 2002
115.	Meyers Lexikon der Technik und der exakten Naturwissenschaften, page 1551
116.	Jensen, K.A., Almen Kemi, 1969, pgs. 328-330
117.	Declaration of Ejvind J. Christiansen, 10/25/02
118.	Conclusions 4-11 of the President of the District Court of the Hague, M. Y. Bonneur, 4/12/02
119.	Pleading Notes, Mr. Hendrick, District Court hearing, 3/22/02, ¶¶ 54-56
120.	Witness Statement of Stanley Michael Roberts, June 2003

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121.	HARWOOD et al., Experimental Organic Chemistry, 2d. ed., pp. 135-136 (1999)
122.	Search results: CSD version 5.23 (April 2002) database, "citalpram3," 10/4/02
123.	Deutsches Patent - und Markenamt, 4/3/02, DE 101 09 042.5-44
124.	PRV, Awapatent, Underrattelse Enl §19 Patentlagen, 2012026, 3/20/02
125.	Decision from Landgericht Munchen I, 10/9/02
126.	Declaration of Prof. Dr. Herwig Schottenberger, 10/7/02
127.	Statement of Peter Somfai, Professor, 7/4/02
128.	Pleading Notes, District Court at The Hague, Case No. KG 02/179, 3/22/02
129.	Grunden & Gozzo, Mal nr T 7589-02 Novartis Sverige AB /. H. Lundbeck A/S, 5/31/02
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133.	Beyer & Walter, Handbook of Organic Chemistry, pp. 3-4 (1996)
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135.	District Court Decision, DE RECHTBANK TE'S-GRAVENHAGE, 12/23/02
136.	Report by C. J .J. van Loon, dated 2/29/02
137.	Declaration of R. N. Kankan, Cipla, 3/15/02
138.	Vogel, Practical Organic Chemistry, 4 <sup>th</sup> ed., pp. 100-124 (1986)
139.	Seventh Report of Dr. Robert Michael Adlington, 8/12/03
140.	Exhibit "RMAM-7" To the 7th Report of Dr. Adlington: The Concise Oxford Dictionary, 7 <sup>th</sup> ed. (1982), pp. 79-80
141.	Exhibit "RMAM-8" To the 7th Report of Dr. Adlington: Bob McDuell, A-Level Chemistry, Course Companion (1991) pp.45-47
142.	Exhibit "RMAM-9" To the 7th Report of Dr. Adlington: Vogel's Textbook of Practical Organic Chemistry, 5 <sup>th</sup> ed. (1989), pp. v-vii, xvi-xix, xxi-xxiii, 131-144
143.	Exhibit "RMAM-13" To the 7th Report of Dr. Adlington: "Calculation of the theoretical conversion of the Diol to Citalopram in Example 3 of '066 using 7.5ml of methanesulfonyl chloride, Conclusion: the MeSO <sub>2</sub> Cl is in excess (118.5%)"
144.	Exhibit "RMAM-14" To the 7th Report of Dr. Adlington: "Calculation of the theoretical conversion of the Diol to Citalopram in Example 3 of '066 using 7.5ml of methanesulfonyl chloride, Conclusion: there is a 20% deficiency of MeSO <sub>2</sub> Cl (100-80=20)"
145.	Exhibit "RMAM-15" To the 7th Report of Dr. Adlington: "Calculation of the yield on going from the Diol to Citalopram Hydrobromide in Example 3 of '066"
146.	Exhibit "RMAM-16" To the 7th Report of Dr. Adlington: "Calculation of the % Yield on going from crystalline Citalopram free base to the hydrobromide salt in Example 3 of '066"
147.	Exhibit "RMAM-17" To the 7th Report of Dr. Adlington: "Calculation of theoretical % Yields on going from the Diol to the hydrobromide salt in Example 3 of '066 with two amendments to the stated protocol"
148.	Exhibit "RMAM-18" To the 7th Report of Dr. Adlington: "Explanation of the discrepancy in the amounts of starting materials used and yield of Citalopram oxalate stated in Example 1 of '926"

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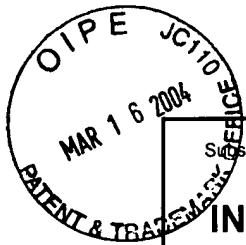


Substitute for form 1449A/B/PTO				<b>Complete if Known</b>	
				Application Number	10/750,049
				Filing Date	December 30, 2003
				First Named Inventor	Hans Petersen
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	6	of	7	Attorney Docket Number	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>					

149.	Exhibit "RMAM-19" To the 7th Report of Dr. Adlington: "Explanation of the discrepancy in the amount of sodium cyanide stated to have been used in Example 1 of '926"
150.	Exhibit "RMAM-20" To the 7th Report of Dr. Adlington: "Calculation of the purity of the 1,1-di-(p-chlorophenyl)-4-dimethyl amino-1-butanol produced in Example 10 of Croxall"
151.	Exhibit "RMAM-22" To the 7th Report of Dr. Adlington: Leo A. Paquette, Encyclopedia of Reagents for Organic Synthesis, Vol. 5, L-M (1995), preface, foreword, pp.3307-3312
152.	Exhibit "RMAM-23" To the 7th Report of Dr. Adlington: Vogel's Textbook of Practical Organic Chemistry, 5 <sup>th</sup> ed. (1989), pp. 165-168
153.	Exhibit "RMAM-29" To the 7th Report of Dr. Adlington: "Detailed Description of the Steps taken and Observations made During Lundbeck's Experiments" (June 2003)
154.	Exhibit "RMAM-30" To the 7th Report of Dr. Adlington: "List of Chemicals"
155.	Exhibit "RMAM-31" To the 7th Report of Dr. Adlington: "Photographs taken during the addition of Methanesulfonyl chloride"
156.	Exhibit "RMAM-32" To the 7th Report of Dr. Adlington: "Photograph taken during equilibration with Ice Cooling"
157.	Exhibit "RMAM-33" To the 7th Report of Dr. Adlington: Aldrich Handbook of Fine Chemicals and Laboratory Equipment (2003-2004), pp.617-619
158.	Exhibit "RMAM-34" To the 7th Report of Dr. Adlington: "Photograph of Dr. Adlington wearing the items of clothing insisted on by Lundbeck"
159.	Declaration of Trevor Laird, 3/6/02
160.	Declaration of Hans Petersen, 5/6/02
161.	Declaration of Dr. Ulrich Riederer, 1/8/03
162.	Declaration of Dr. Ulrich Riederer, 1/14/03
163.	Expert Report of Karl Anker Jørgensen, 8/18/03
164.	Second Expert Report of Karl Anker Jørgensen, 9/20/03
165.	Schedule A - Experiments (Annex to the 7th Report of Dr. Adlington)
166.	Mortensen et al., <i>Journal of Neurochemistry</i> 79:237-247 (2001)
167.	Ohman et al., <i>Journal of Chromatography B</i> 753:365-373 (2001)
168.	Impurities in New Drug Substances Q3A(R), International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 2/7/02
169.	Hansen et al., <i>European Journal of Pharmacology</i> 352:307-315 (1998)
170.	Hansen et al., <i>The Journal for Pharmacology and Experimental Therapeutics</i> , 283:1333-1341 (1997)
171.	Bigler et al., <i>European Journal of Med. Chem. - Chimica Therapeutica</i> Vol. 12, No. 3, pp. 289-295 (May-June 1997)
172.	Kelliher et al., <i>Psychoneuroendocrinology</i> 28:332-347 (2003)
173.	Third Report of Dr. Robert Michael Adlington
174.	EPO Communication of 12 February 2002, Application No. 01 909 568.6-2117
175.	Decision from Stockholm Tingsret dated 5 June 2002, PROTOKOLL
176.	EPO Communication of 13 September 2002, Application No. 02 009 350.6-2117

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177.	Test results H. Lundbeck A/S faxed to EPO 17.01.02
178.	Letter from Hoffman Eitle to EPO 6 May 2002, European Patent App. No. 01 909 568.6-2117
179.	Betænkning/office action from DK PTO of 15 October 2001, PATENT-OG VAREMÆRKESTYRESLSEN, Leila Nielsen
180.	H. Lundbeck A/S amendments, EP-A-347 066, with letter from S. J. Wilkinson (June 17, 1994)
181.	H. Lundbeck A/S reply to official action from EPO - dated 17 January 2002, EP application no. 01 909 568.6-2117, John Meidahl Petersen
182.	Alkaloid Chemistry, Budapest, Ungarn (May 10, 2003 ), Expert Opinion of Prof. Dr. Csaba Szantay re: Reproduction of Example 3 of the EP 347066 B1 European patent
183.	Stockholm Tingsräts decision (May 31, 2002), PROTOKOLL
184.	EPO examination report (January 10, 2002), Application No. 01 909 568.6-2117
185.	Writ for Registration, Van Mastrigt & Partners, 3/22/03
186.	Decision from Stockholm Tingsret dated 5 June 2002, PROTOKOLL
187.	Report re: Dutch patents NL 1016435 and NL 1017413
188.	Correspondence [with the Finnish Patent Office] re patent in suit, PATENT-OCH REGISTERSTYRELSEN, FORELAGGANDE, November 10, 2001
189.	Minutes from EPO oral hearing 24 May 2002 and approved corrections
190.	Telephone Conference Report from EPO re: Appl. No. 01 909 568.6 (February 26, 2002)
191.	Aterkallelse av ansökan PCT/EP00/06426; Notarbartolo & Gervasi
192.	Lundbecks anförsande i rättegången i Nederländerna mot Tiefenbacher och GEAs moderbolag Hexal Pharma
193.	Lundbecks svaromål i mål T 7589-02, 2002-05-24, SANDART & PARTNERS ADVOKATBYRA
194.	Organikum Organisch-Chemisches Grundpraktikum (1975, 14th edition )

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